

REMARKS

The specification has been amended to correct an obvious error at page 22, lines 11-12, to indicate the correct SEQ ID NOs, as it was clearly the sequences of the nucleic acids that were meant, not the sequences of the polypeptides.

Claims 1-45, 68 and 137 have been canceled. Claims 47, 49, 51, 52, 54-60, 62, 67 and 134 have been amended. Claims 140-156 have been added. Support for Claim 140 is on page 7, lines 18-21. Support for Claims 141 and 142 is on page 2, lines 15-16. Support for Claims 143 and 145 is on page 7, lines 18-24. Support for Claims 144 and 146 is to be found on page 12, lines 9-20 (hybridization conditions) and on page 22, lines 10-12. Support for Claim 147 can be found on page 7, lines 7-10 and page 13, lines 1-3. Support for Claims 148 and 149 is on page 47, line 25 to page 48, line 4. Support for Claims 150-153 is on page 49, line 15 to page 50, line 7 and on page 50, lines 21-27. Support for Claim 154 is on page 50, lines 8-13. Support for Claims 155 and 156 is found on page 47, lines 8-24; page 10, line 18 to page 11, line 5; and page 14, lines 1-8. No new matter has been added.

Rejection of Claims 47-52, 54-62, 65, 67-71 and 134-139 Under 35 U.S.C. § 112, First Paragraph

Claims 47-52, 54-62, 65, 67-71 and 134-139 have been rejected under 35 U.S.C. § 112, first paragraph, as it is said that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate with these claims.

Claims 68 and 137 have been canceled.

Claims 47, 54, 57, 60, 62 and 67 have been amended. Claims 70 and 71 are dependent on Claim 67. As amended, these claims refer to isolated nucleic acids, nucleic acid vectors and cultured cells in which the nucleic acid has at least 90% nucleotide sequence identity to nucleic acid encoding SEQ ID NO:6 or to SEQ ID NO:5. In either case, the polypeptide must have iron transport activity, which can be determined as described on page 59, lines 14-23 and in Figure 3 of the specification. It would not be difficult for one of ordinary skill in the art to identify by hybridization experiments or to modify the described nucleic acids to fit the requirements of

Claims 47, 54, 57, 60, 62 or 67, and test for iron transport activity of the encoded polypeptide. A method for this test is described on page 51, lines 1-24 of the specification. This would not amount to undue experimentation.

Claims 48 and 61 refer to the coding sequence or coding region of the human Ferroportin1 gene. This region is well defined and can be found in SEQ ID NO:5 of the Sequence Listing as filed. As this region is known to encode a functional iron transport protein and has a fully defined nucleotide sequence, one of ordinary skill in the art would know how to make and use the invention.

Claims 50, 52, 135, 136, 138 and 139 are drawn to isolated nucleic acids comprising a portion of SEQ ID NO:5 or a nucleic acid complementary to, or highly similar to, SEQ ID NO:5, or are drawn to isolated nucleic acids comprising a portion of SEQ ID NO:7. While there may be many members of the class of nucleic acids for each of these claims, they are well defined by sequence, such that one of ordinary skill in the art would know how to make the invention from methods known in the art. Methods of using the nucleic acids of the invention are described, for example, on page 45, line 21 to page 50, line 27. It is not necessary for the nucleic acids of the invention to all encode a functional protein to have a use that one of ordinary skill in the art would know how to carry out. Portions of a Ferroportin1-specific nucleic acid can be used as primers and probes and control target nucleic acids in amplification and hybridization methods to distinguish between a gene with a wild type sequence and a variant gene that could encode a protein resulting in defective iron transport.

Claims 49, 51, 56, 59 and 134 have been amended. As amended, they refer to definite sequences or to nucleic acids defined by hybridization properties. High stringency conditions are explained on page 12, lines 15-25. Thus, it should also be clear to one of ordinary skill in the art how to produce and use the cultured cells of Claim 65 and 69, with all the necessary methods to make and test such a cell for the required function readily available to one of ordinary skill. With the sequences SEQ ID NO:5 and SEQ ID NO:7 being described by Applicants, it is easy for one of ordinary skill in the art to identify and isolate nucleic acids that encode allelic variants of the Ferroportin1 protein, and to use these nucleic acids to identify and characterize the difference between SEQ ID NO:5 and the allelic variant, or the difference between SEQ ID NO:7 and the

allelic variant. See, for example, page 47, line 25 to page 49, line 14 for methods of identifying and characterizing allelic variants.

Claims 55 and 58 have been amended, although Applicants disagree with the assessment that the specification is not enabling for portions of amino acid sequence SEQ ID NO:6. One of ordinary skill in the art would have ample instruction, from a combination of the specification and sources available in the scientific literature, to make and use the isolated nucleic acid and the nucleic acid vector of the claims.

Interview Summary

A telephonic interview was conducted on March 30, 2004. Participants were:

Examiner Sandra L. Wegert

Primary Examiner Elizabeth C. Kemmerer

Attorney Doreen M. Hogle

Attorney Carol A. Egner

The attorneys wish to thank the Examiners for holding the interview and for their helpful suggestions.

The Attorneys pointed out to the Examiners that the claims under examination are drawn to nucleic acids that correspond to a human gene that has been identified as being associated with the iron transport function which is defective in hemachromatosis. See Montosi *et al.*, *The Journal of Clinical Investigation* 108(4):619-623, August, 2001 (reference AW2 of Supplemental Information Disclosure Statement).

The Examiners suggested that claims encompassing the complements of the nucleic acids in the allowable claims 46 and 72 should be allowable. Claims to nucleic acids that hybridize under specific conditions to the nucleic acids of allowable claims 46 and 72 will be considered.

It was emphasized to the Examiners that although an iron transport function has been associated with the gene product encoded by the human ferroportin1 gene, nucleic acids that correspond to less than the full length ferroportin1 gene, or correspond to a full length ferroportin1 gene not having iron transport protein, would still be useful in ways known to one of ordinary skill in the art. Page 45, line 21 to page 50, line 27 describes multiple methods for how

one of ordinary skill in the art would make and use nucleic acids of the claims to identify those with variant nucleotide sequences compared to the wildtype sequence.

CONCLUSION

The Examiner is requested to consider the above amendments and remarks, and withdraw the remaining rejection. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Carol A. Egner
Carol A. Egner
Registration No. 38,866
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133

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